



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0489; FRL-9341-6]

RIN 2070-AJ88

Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances:

Hexabromocyclododecane (Chemical Abstracts Service Registry Number (CASRN) 25637-99-4) and 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6), hereinafter collectively referred to as HBCD. This proposed rule would designate “use in consumer textiles, other than for use in motor vehicles” as a significant new use. This action would require persons who intend to manufacture (including import) or process HBCD for use in covered consumer textiles to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if appropriate, to prohibit or limit that activity before it occurs. For this proposed rule, the general SNUR article exemption for persons who import or process chemical substances as part of an article would not apply.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0489, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2011-0489. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0489. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of

your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW, Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Sue Slotnick, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1973; email address:

slotnick.sue@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process HBCD for consumer textiles. Potentially affected entities may include, but are not limited to organizations identified by the following North American Industry Classification System (NAICS) codes:

- Chemical Manufacturing (NAICS code 325).
- Painting and Wall Covering Contractors (NAICS code 238320).
- Textile and Fabric Finishing (except Broadwoven Fabric) Mills (NAICS code 313312).
- Curtain and Drapery Mills (NAICS code 314121).
- Other Household Textile Product Mills (NAICS code 314129).
- All Other Miscellaneous Textile Product Mills (NAICS code 314999).
- Upholstered Household Furniture Manufacturing (NAICS code 337121).
- Household Furniture (except Wood and Metal) Manufacturing (NAICS code 337125).
- Mattress Manufacturing (NAICS code 337910).
- Blind and Shade Manufacturing (NAICS code 337920).
- Furniture Merchant Wholesalers (NAICS code 423210).
- Home Furnishing Merchant Wholesalers (NAICS code 423220).

- Reupholstery and Furniture Repair (NAICS code 811420).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

In addition, chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that shipments of chemical substances comply with all applicable rules and orders under TSCA, including SNURs. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or

CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing a SNUR for HBCD which would require persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of HBCD for use in consumer textiles other than for use in motor vehicles. EPA is considering future regulatory action on additional uses of HBCD.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering “all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance,
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.”

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit II.C., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. Additional provisions appear at § 721.1(c) which describe how persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, the Agency may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, the Agency is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

EPA proposes that a person who imports or processes HBCD as part of an article for use in consumer textiles (except for use in motor vehicles) would not be exempt from submitting a SNUN. (See rationale at Unit VI.C.) For this reason, § 721.45(f), which exempts persons importing or processing a chemical substance as part of an article, would not apply to this proposed SNUR.

Persons who export or intend to export a chemical substance(s) identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import chemical substances are subject to the TSCA section 13

import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance(s) comply with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

III. Overview of HBCD

A. What Chemicals are Included in the Proposed SNUR?

This proposed SNUR would apply to two chemical substances: Hexabromocyclododecane (CASRN 25637-99-4) and 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6). Hexabromocyclododecane is manufactured by adding bromine to technical grade 1,5,9-cyclododecatriene to make a chemical substance where the positions of the six bromine atoms are not specified on the cyclododecane ring, corresponding to CASRN 25637-99-4. The specific 1,2,5,6,9,10-hexabromocyclododecane isomer (CASRN 3194-55-6) is the major component of CASRN 25637-99-4. Throughout this proposed rule, the term “HBCD” represents both chemical substances, unless a specific CASRN is also noted.

B. What is the Production Volume of HBCD?

The Inventory Update Rule (IUR)¹ submissions to EPA reported annual U.S. import/production volumes of 10-50 million pounds (lb) in both 2002 and 2006 for CASRN 3194-55-6 (EPA, 2006). IUR submissions to EPA reported annual U.S. import/production volumes of 10,000 to 500,000 lb in 2002 for CASRN 25637-99-4; no import/production was reported in 2006 (EPA, 2006).

¹ As of August 16, 2011, the Inventory Update Rule (IUR) was renamed “Chemical Data Reporting rule (CDR).” See the TSCA Inventory Update Reporting Modifications; Chemical Data Reporting final rule in the **Federal Register** issue of August 16, 2011 (76 FR 50816) (FRL-8872-9).

C. What are the Uses of HBCD?

Based on information gathered from research, industry, and government, EPA believes that HBCD is not used in consumer textiles other than for use in motor vehicles. The major use of HBCD is in polystyrene foam insulation boards used in construction. It is also used to a minor extent in high-impact polystyrene in electronic products and in textile coatings in carpets, vehicles, furniture, and upholstery, such as draperies (Posner, 2006). In the IUR data, one manufacturer/importer of HBCD (CASRN 3194-55-6) reported the use of the chemical substance under the NAICS code for textile and fabric finishing mills (EPA, 2006). For this use, 1% of the total production volume of the chemical substance was in consumer and commercial products. However, the reporting does not distinguish between commercial and consumer use (EPA, 2006).

Information available to EPA indicates that the use of HBCD in textiles is as a backcoating to function as a flame retardant. EPA conducted preliminary research to determine whether HBCD was used in textile applications for end products sold to consumers. In 2010, an HBCD expert with the Consumer Product Safety Commission (CPSC) expressed to EPA his understanding that HBCD is used only in non-consumer textiles such as firefighters' suits (CPSC, 2010). In 2011, EPA requested information from current and former manufacturers of HBCD. The responses indicate that only one manufacturer sells HBCD for textile uses. The company does not know whether the end use of any of those textiles is a consumer article. (ACC, 2011). Additionally, a representative of the furniture manufacturing company Herman Miller told EPA that HBCD is not in their products (Herman Miller, 2011). EPA also received information from a group of textile formulators that the end uses of HBCD-containing textiles are for military, institutional, and aviation uses only (EPP, 2011). EPA solicits comment on

whether any of these uses could be considered consumer textile uses. (See definition of “consumer textile” at § 721.10281 in the regulatory language of this proposed rule).

EPA found that a small amount of HBCD is used in floor mats, headliners, and possibly other interior fabrics in motor vehicles made in the United States, including passenger vehicles. The automotive industry plans to phase out these uses in 2015. This phase-out is consistent with the addition of HBCD to the Annex XIV List of Substances Subject to Authorisation under the European Union’s Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) regulations (REACH, 2011). See http://echa.europa.eu/reach_en.asp. The REACH regulations are expected to effectively ban the use of HBCD by major U.S. automotive companies unless authorized for use in the European Union (EU) after July 21, 2015. The companies are not likely to manufacture a different set of products for sale in the EU and for sale in the United States. Because the use of HBCD in textiles in motor vehicles is currently ongoing, that use is not included in this proposed rule.

Based on the sum of available information, EPA believes HBCD is not used in consumer textiles other than those used in motor vehicles. The Agency also believes HBCD could potentially be used in the future in consumer textiles in the United States because the chemical substance:

1. Is used in non-consumer textile applications in the United States including institutional, military, and aviation uses.
2. Is used in textiles in motor vehicles in the United States.
3. Has been used in residential consumer textile applications.

See more information on uses of HBCD in EPA’s “Economic Analysis of the Proposed Significant New Use Rule for Hexabromocyclododecane (HBCD)” (EPA, 2011).

D. What are the Potential Health and Environmental Effects of HBCD?

1. *Human health effects.* Repeated exposure of HBCD to rats showed disturbances in thyroid hormone system and effects on the thyroid in males and females (Chengelis, 2001). A study by Eriksson, et al. (2006), concluded that neonatal exposure of HBCD to mice affected spontaneous motor behavior, learning and memory processes in adult mice. However, this study was not conducted according to established Organization for Economic Cooperation and Development (OECD) Test Guidelines.

In a recently conducted, more robust, 2-generation reproductive toxicity study in rats conducted according to established OECD test guidelines, HBCD showed treatment-related reproductive effect (a significant decrease in the number of primordial follicles in the F1 females) (Ema, et al., 2008). Although this decrease in ovarian follicles did not affect any reproductive parameters in this study, this effect is suggestive of potential reproductive toxicity. Developmental effects were observed including delays in eye opening in the second (F2) generation and transient changes in learning and memory in F1 males, but exposure did not cause any changes in spontaneous behavior. In addition, there was high and dose-dependent pup mortality during lactation (Ema, et al., 2008).

2. *Environmental effects.* Laboratory studies have shown that HBCD is capable of producing adverse effects in a variety of organisms including algae, fish, invertebrates, and soil-dwelling organisms at environmentally relevant concentrations. HBCD is toxic to algae and acutely toxic to fish embryos (Desjardins, et al., 2004 and Deng, et al., 2009). A number of sub-lethal effects (e.g., altered thyroid status, protein metabolism, oxidative stress, reproductive activity) have also been observed in fish (Palace, et al., 2008; Kling et al., 2009; Zhang, et al., 2008; and Ronisz, et al., 2004). One study reported a reduced number and size of daphnid offspring in first and second generations

(Drottar, 1998). Thyroid hormone-dependent developmental effects were observed in tadpoles (*Xenopus laevis*) exposed to HBCD (Schriks, et al., 2006). HBCD has been reported to reduce egg production and lower biomass in soil dwelling organisms (*Lumbriculus variegatus*) (Oetken, et al., 2001). HBCD administered to chicken (*Gallus domesticus*) embryonic hepatocytes *in vitro* resulted in significant alterations in expression of genes (mRNA) associated with liver and thyroid function (Crump, et al., 2008). Thinner egg shells were measured in American kestrels exposed to a combination of polybrominated diphenyl ethers (PBDEs) and HBCD (Ferne, et al., 2009).

E. What are the Potential Sources and Routes of Exposure to HBCD?

Because HBCD is not chemically bound to its substrate (the protected textile material), there is potential for HBCD to be released at any point in the lifecycle. There is potential for release when the HBCD is initially manufactured, when it is being formulated into the material that is commonly used in textile back coatings, as well as when it is being combined with the textile material to which it is added. In addition, HBCD can be released during the service life of the textile material containing it, including release into water used to wash the treated textiles or into the air via dust particulates. Workers and the general population can be exposed to HBCD through direct contact as it migrates across land, in air, and in water by diffusion or environmental transport. Other opportunities for release can occur at the end of the lifecycle of the consumer articles when they are transported as waste and disposed of, although incineration at high temperatures destroys the HBCD (Posner, 2006).

Evidence strongly suggests there is potential for exposure to the general population from HBCD in the environment and also from products and dust in the home and workplace. HBCD is found world-wide in the environment and wildlife. Human

exposure is evidenced from its presence in breast milk, adipose tissue, and blood (Covaci, et al., 2006). The chemical substance bioaccumulates and biomagnifies in food chains. The frequent detection of HBCD over a large geographic area, with increasing exposure in remote locations such as the Arctic, where no demonstrable local sources exist that can account for these exposures, suggest that HBCD is persistent and undergoes long-range transport (UNEP, 2007).

To the extent HBCD is present in household applications (e.g., building foam, furniture upholstery, carpeting), children could be exposed, especially given children's increased exposure via dust and the hand-to-mouth ingestion pathway. *In vitro* experiments conducted to demonstrate leaching of HBCD from textiles showed that the presence of simulated biological fluids (sweat, saliva) and fruit juices enhances the leaching of HBCD from back-coated samples (Ghanem, 2009). Children's exposure to HBCD from mouthing of textiles and from ingestion of dust has been estimated (EC, 2008).

HBCD has been measured in air and sediment in Scandinavian countries, North America and Asia (Covaci, et al., 2006 and Arnot, et al., 2009). HBCD has also been measured in marine and arctic mammals, freshwater and marine fish, aquatic invertebrates, birds and bird eggs, and one plant species (Covaci, et al., 2006 and Arnot, et al., 2009). HBCD has been detected in Arctic air in northern Scandinavia and in Arctic birds and bird eggs, Arctic fish, ringed seals and polar bears (UNEP, 2009). It has been detected in freshwater, marine, and avian organisms, and in upper trophic-level mammals (polar bears and seals).

For more information on HBCD concerning its physical-chemical properties, fate, releases, and human and environmental exposure, see EPA's "Hexabromocyclododecane

(HBCD) Action Plan” dated August 18, 2010 (HBCD Action Plan, 2010).

IV. Summary of Proposed Rule

EPA is proposing to designate as a significant new use any use of HBCD in consumer textiles other than for use in motor vehicles. EPA believes the only current use of HBCD for consumer textiles is in motor vehicles. Thus any use of HBCD in consumer textiles (other than for textiles in motor vehicles) would be a significant new use. A proposed definition of “consumer textile” can be found at § 721.10281 of the regulatory text of this proposed rule. The proposed definition of “motor vehicle” refers to 40 CFR 85.1703.²

This proposed rule would add a section to 40 CFR part 721 to require persons who intend to manufacture (including import) or process HBCD for an activity preliminarily designated as a significant new use by this action to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if appropriate, to prohibit or limit that activity before it occurs. For this proposed rule, the general SNUR exemption for persons that import or process chemical substances as part of an article at § 721.45(f) would not apply. (See discussion at Unit VI.C.)

² The definition at 40 CFR 85.1703 is: “a vehicle which is self-propelled and capable of transporting a person or persons or any material or any permanently or temporarily affixed apparatus shall be deemed a motor vehicle, unless any one or more of the criteria set forth below are met, in which case the vehicle shall be deemed not a motor vehicle and excluded from the operation of the [Clean Air] Act: (1) The vehicle cannot exceed a maximum speed of 25 miles per hour over level, paved surfaces; or (2) The vehicle lacks features customarily associated with safe and practical street or highway use, such features including, but not being limited to, a reverse gear (except in the case of motorcycles), a differential, or safety features required by state and/or federal law; or (3) The vehicle exhibits features which render its use on a street or highway unsafe, impractical, or highly unlikely, such features including, but not being limited to, tracked road contact means, an inordinate size, or features ordinarily associated with military combat or tactical vehicles such as armor and/or weaponry.”

40 CFR 85.1703 is available online at: <http://www.gpo.gov/fdsys/pkg/CFR-2000-title40-vol12/xml/CFR-2000-title40-vol12-sec85-1703.xml>.

V. Significant New Use Determination

A. Rationale

As summarized in Unit III.D. and E., EPA has concerns regarding the potential exposure to and human health and environmental effects of HBCD. EPA believes that HBCD could be manufactured or processed for consumer textiles other than for use in motor vehicles in the future. Accordingly, EPA wants the opportunity to evaluate and control, where appropriate, activities associated with that use, if such manufacturing or processing were to be commenced in the future. The required notification provided by a SNUN would provide EPA with the opportunity to evaluate activities associated with the significant new use and an opportunity to protect against unreasonable risks, if any, from exposure to HBCD.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the new use, the SNUN to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

B. Objectives

Based on the considerations in Unit V.A., EPA has the following objectives with regard to the significant new use that is preliminarily designated in this proposed rule:

1. EPA would receive notification of any person's intent to manufacture (including import) or process HBCD for the described significant new use before that activity begins.
2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the SNUN submitter begins manufacturing or processing of HBCD for the described significant new use.
3. EPA would be able to regulate prospective manufacturers or processors of HBCD before the described significant new use of the chemical substance(s) occur, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

C. Relevant Factors Considered for this Proposed SNUR

TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including those listed at TSCA section 5(a)(2) (see list at Unit II.B.). EPA has preliminarily determined that manufacturing or processing of HBCD for use in consumer textiles other than for use in motor vehicles is a significant new use. This determination is based primarily on the following factor listed at TSCA section 5(a)(2): "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance." The latest information available to EPA indicates that the only ongoing use of HBCD in consumer textiles is for use in motor vehicles. Initiation of new uses of HBCD in consumer textiles could increase the magnitude and duration of exposure to the general population from HBCD in the environment and from products and dust in the home and workplace. Workers could be exposed to HBCD at facilities of all types involved in the lifecycle of the products, as described in greater detail in Unit III.E. Releases to the environment are expected to occur during the service

life of the textiles containing HBCD. Such increase in releases could contribute additional HBCD to the atmosphere, long-range transport, and greater concentrations in water, which could be detrimental to overall environmental and human health. Thus, EPA believes that initiating the use of HBCD in consumer textiles other than for use in motor vehicles would increase the magnitude and duration of exposure to humans and the environment over that which would otherwise exist.

D. Request for Comment

EPA welcomes comment on all aspects of this proposed rule, including:

1. The basis for the significant new use determination presented for this proposed rule.
2. Information about any ongoing manufacture, import, or processing of HBCD for use in consumer textiles.

VI. Alternative Regulatory Approaches

Before proposing this SNUR, EPA considered the following alternative regulatory actions:

A. Promulgate a TSCA Section 8(a) Reporting Rule

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for HBCD in consumer textiles, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the use in consumer textiles and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f)

to prohibit or limit the activity before it begins, if warranted. In addition, EPA might not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of health and environmental concerns related to HBCD, if used for the proposed significant new use, EPA believes that a TSCA section 8(a) rule for these chemical substances would not meet EPA's regulatory objectives.

B. Regulate HBCD in Consumer Textiles Under TSCA Section 6

EPA may regulate under TSCA section 6 if “the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment.” (TSCA section 6(a)). EPA concluded that risk management action under TSCA section 6 is not necessary at this time because EPA:

1. Believes HBCD is not being used in consumer textiles in the United States, other than for use in motor vehicles.
2. Has not determined as of this date that use of HBCD in motor vehicles presents unreasonable risk.
3. Expects the use in motor vehicles to end within a few years. This proposed SNUR would allow the Agency to address the potential risks associated with the proposed significant new use.

C. Allow the Exemption for Persons Who Import or Process HBCD as Part of Articles that Would be Subject to the Proposed SNUR

Under the SNUR exemption provision at § 721.45(f), a person who imports or processes a chemical substance covered by a SNUR identified in 40 CFR part 721,

subpart E, as part of an article is not generally subject to the notification requirements of § 721.25 for that chemical substance. However, EPA is concerned that exempting HBCD as part of articles would render the SNUR less effective because of the possibility that consumer textile articles containing HBCD, the primary concern of EPA associated with this proposed rule, could be imported or processed for uses subject to this proposed SNUR without the submission of a SNUN. This proposed rule would not include the exemption at § 721.45(f).

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notification requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of the chemical substance(s) (including manufacturing or processing the chemical substance(s) as part of an article) for a use that would be regulated through this proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notification requirements and wait until the notification review period, including all extensions, expires. EPA has promulgated provisions (§ 721.45(h)) to allow persons to submit a SNUN before the effective date of the SNUR. If a person were to meet the conditions of

§ 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, import, or processing of the chemical substance between publication of the proposed rule and the effective date of the final SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the final rule. To resume their activities, these persons would have to comply with all applicable SNUN requirements and wait until the notification review period, including all extensions, expires.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (TSCA section 5(d); 40 CFR 720.50 and 40 CFR 721.25). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-SNUN consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the

likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new use of the chemical substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 40 CFR 721.25. The e-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of HBCD in consumer textiles. The evaluation is in the “Economic Analysis of the Proposed Significant New Use Rule for Hexabromocyclododecane (HBCD)” (EPA, 2011). It is briefly summarized here and is available in the docket for this proposed rule.

Because there appears to be no use of HBCD in consumer textiles in the United

States at the current time, other than for use in motor vehicles, EPA expects very few, if any, entities would submit a SNUN. As a result, the economic impact of this rule is anticipated to be either zero or very low.

In the event that a SNUN is submitted, costs are estimated at approximately \$8,300 per SNUN submission for large businesses and \$5,900 for small businesses, and include the cost to prepare and submit the SNUN and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). In its evaluation of this proposed rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

XI. References

The following documents are specifically referenced in the preamble for this proposed rule. In addition to these documents, other materials may be available in the docket established for this proposed rule under docket ID number EPA-HQ-OPPT-2011-0489, which you can access through <http://www.regulations.gov>. Those interested in the information considered by EPA in developing this proposed rule, should also consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether the other documents are physically located in the docket.

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XII. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this action has been designated a “significant regulatory action.” Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563, entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011), and any changes

made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of the Executive Order.

EPA has prepared an economic analysis of this action, entitled “Economic Analysis of the Proposed Significant New Use Rule for Hexabromocyclododecane (HBCD)” (EPA, 2011). A copy of the document is available in the docket for this proposed rule and is summarized in Unit X.

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for certain EPA regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 97 hours per response. This burden estimate includes the time needed to review instructions; search existing data sources; gather and maintain the data needed; and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. Small entity is defined in accordance with section 601 of RFA as: A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. For purposes of assessing the impacts of this proposed rule on small entities, EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency estimated potential impacts on small business.

A SNUR applies to any person (including small or large entities) who intends to manufacture, import, or process a chemical substance for a use the EPA has designated as a "significant new use." By definition of the word "new," and based on information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since this proposed SNUR would require a person who intends to engage

in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of SNUNs per year. For example, the number of SNUNs was four in Federal fiscal year 2005, eight in FY2006, six in FY2007, eight in FY2008, and seven in FY2009. During this 5-year period, three small entities submitted a SNUN. Therefore, EPA believes that the potential economic impact of complying with a SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531-1538).

E. Federalism

This action would not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Indian Tribal Governments

This action would not have tribal implications as specified in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). This action is not expected to have substantial direct effects on Indian Tribes, would not significantly or uniquely affect the communities of Indian Tribal governments, and would not involve or impose any requirements that affect Indian Tribes. Thus, Executive Order 13175 does not apply to this action.

G. Protection of Children

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Effect on Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. Technical Standards

Because this action would not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note), does not apply to this action.

J. Environmental Justice

This action would not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 20, 2012.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10281 to subpart E to read as follows:

§ 721.10281 Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified as hexabromocyclododecane (CASRN 25637-99-4) and 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6) are subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is use in consumer textiles, other than for use in motor vehicles.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Definitions.* The definitions in § 721.3 apply to this section. In addition, the following definitions apply:

Consumer textile means any cloth, fabric, or other item produced during the milling process (including spinning, weaving, knitting, felting, or finishing), consisting in whole or in part as a product that is sold to or made available to a private individual who uses the product in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment. Consumer textiles include, but are not limited to, upholstered household furniture, mattresses, and draperies.

Motor vehicle has the meaning found at 40 CFR 85.1703.

(2) *Revocation of article exemption.* The provisions of § 721.45(f) do not apply to

this section. A person who imports or processes the chemical substances identified in paragraph (a)(1) of this section as part of an article for the significant new use described in paragraph (a)(2) of this section must submit a significant new use notice (SNUN).

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